

Amendment and Response

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Serial No.: 09/834,110

Confirmation No.: 5306

Filed: April 12, 2001

For: TREATMENT OF DISORDERS BY IMPLANTING STEM CELLS AND/OR PROGENY THEREOF INTO GASTROINTESTINAL ORGANS**Remarks**

The Office Action mailed December 18, 2003 has been received and reviewed. Claims 25, 26, 31-33, 35, 37, 39-41, and 44 having been amended, claims 46-49 having been added, and claims 21-24, 27-30, 34, 36, 38, and 42 having been canceled, the pending claims are claims 25, 26, 31-33, 35, 37, 39-41, 43-49. Reconsideration and withdrawal of the rejections are respectfully requested. Support for amended claims 25, 26, 31-33, 35, 37, 39-41, and 44 and new claims 46-49 is found throughout the specification. Support for the recitation "administering the cells by local injection" in claims 32 and 33 is found, for example, on page 3, line 22. Applicants reserve the right to continue the prosecution of canceled subject matter in a continuing application.

Examiner Interview

A telephonic interview was held on February 23, 2004 between Examiner Joseph Woitach, Supervisory Patent Examiner Debra Reynolds and Applicants' Representatives Ann Mueting and Nancy Johnson. During this interview, the rejections under 35 U.S.C. §112, first paragraph, and 35 U.S.C. §102 were discussed. Examiners Woitach and Reynolds are thanked for the courtesy of this interview.

Claim Objections

Claims 21-27, and 31-45 are objected to because the election of species was made to a degenerative disorder, however the claims broadly encompass any gastrointestinal alimentary tract disorder. This objection is respectfully traversed. Applicants respectfully note that, according to MPEP § 809.02(a), Applicants' claims will be limited to a single, elected species only if no generic claim is finally held allowable. Thus, it is inappropriate, at this time, to require amendment of the claims, including generic claims, to limit the claims to the elected species only. Withdrawal of this objection of the claims is respectfully requested.

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The 35 U.S.C. §112, First Paragraph, Rejection

The Examiner rejected claim 37 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. However, the Examiner continues with the statement that "[u]pon review of Applicants' comments . . . and supporting portions of the specification, Examiner agrees that the specification supports 'substance P' as recited in the claims" (page 5 of Office Action, mailed December 18, 2003). Thus, it appears that this rejection of claim 37 under 35 U.S.C. §112, first paragraph, has been withdrawn. Clarification of the record is requested. Applicants respectfully submit that the specification provides clear support for providing the neurotransmitter substance P. See, for example, page 2, line 14, page 3, lines 13-20, and page 10, line 29 through page 11, line 11 of the specification. Reconsideration and withdrawal of this rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

The Examiner rejected claims 21-27 and 31-45 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants respectfully traverse this rejection.

Claims 21-24, 27, 34, 36, 38, and 42 have been cancelled. Claims 25, 26, 31, 32, 35, 37, 39, 40, and 44 are drawn to "[a] method of providing a nitric oxide (NO) within the gastrointestinal alimentary tract of a subject suffering from a gastrointestinal disorder associated with lower levels of NO comprising implanting isolated embryonic neural stem cells directly into the gastrointestinal alimentary tract of the subject, wherein the implanted embryonic neural stem cells produce NO." Claims 33, 41, 43, and 45-49 are drawn to "[a] method of treating a disorder of the enteric nervous system in a subject suffering from an enteric nervous disorder associated with lower levels of NO comprising implanting isolated embryonic neural stem cells

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directly into the gastrointestinal alimentary tract of the subject, wherein the implanted embryonic neural stem cells produce NO."

Applicants respectfully submit that the specification provides adequate teaching and guidance for the claimed methods. See, for example, the examples on pages 11-15 of the specification, the Declaration under 37 C.F.R. § 1.132 of Pankaj Jay Pasricha and Maria-Adelaide Micci (submitted with the Amendment and Response filed January 3, 2002) and Exhibits A-D of the Declaration under 37 C.F.R. § 1.132 of Pankaj Jay Pasricha and Maria-Adelaide Micci. Reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. §112, first paragraph, is respectfully requested.

The 35 U.S.C. §112, Second Paragraph, Rejection

The Examiner rejected claim 32 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection. Amended claim 32 is drawn to a method comprising implanting isolated embryonic neural stem cells directly into the gastrointestinal alimentary tract of the subject, "wherein implanting cells into a gastrointestinal alimentary tract of a subject comprises administering the cells by local injection." Applicant's respectfully submit that the metes and bounds of such administration is clear. Withdrawal of this rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

The 35 U.S.C. §102 Rejection

The Examiner rejected claims 21, 22, 28, 29, and 32 under 35 U.S.C. §102 as being anticipated by Luo et al. (*Xenotransplantation* 1998 Aug;5(3): 197-206). The Examiner rejected claims 21, 22, 25, 26, 30, 31, and 32 under 35 U.S.C. §102 as being anticipated by Keller et al. (*J. Invest Surg* 1997 Nov-Dec;10(6): 375-8). Applicants respectfully traverse.

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Claims 21, 22, and 28-30 have been canceled. Claims 25, 26, 31, 32, as amended, all depend from claim 35, drawn to a method of a method "comprising implanting isolated embryonic neural stem cells directly into the gastrointestinal alimentary tract of the subject, wherein the implanted embryonic neural stem cells produce NO." Applicants submit that neither Luo et al. nor Keller et al. disclose "implanting isolated embryonic neural stem cells directly into the gastrointestinal alimentary tract of the subject." Likewise, neither Luo et al. nor Keller et al. disclose "wherein the implanted embryonic neural stem cells produce NO." Thus, Luo et al. and Keller et al. do not set forth each and every element of claims 25, 26, 31, or 32. Withdrawal of this rejection under 35 U.S.C. §102(b) is respectfully requested.

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GASTROINTESTINAL ORGANS**Summary**

It is respectfully submitted that the pending claims 25, 26, 31-33, 35, 37, 39-41, 43-49 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
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By

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 18th day of March, 2004, at 11:30am (Central Time).

By: Cam E. Olson
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